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The Importance of CON

North Carolina General Assembly
Joint Legislative Committee on
Access to Healthcare and Medicaid Expansion
April 11, 2022

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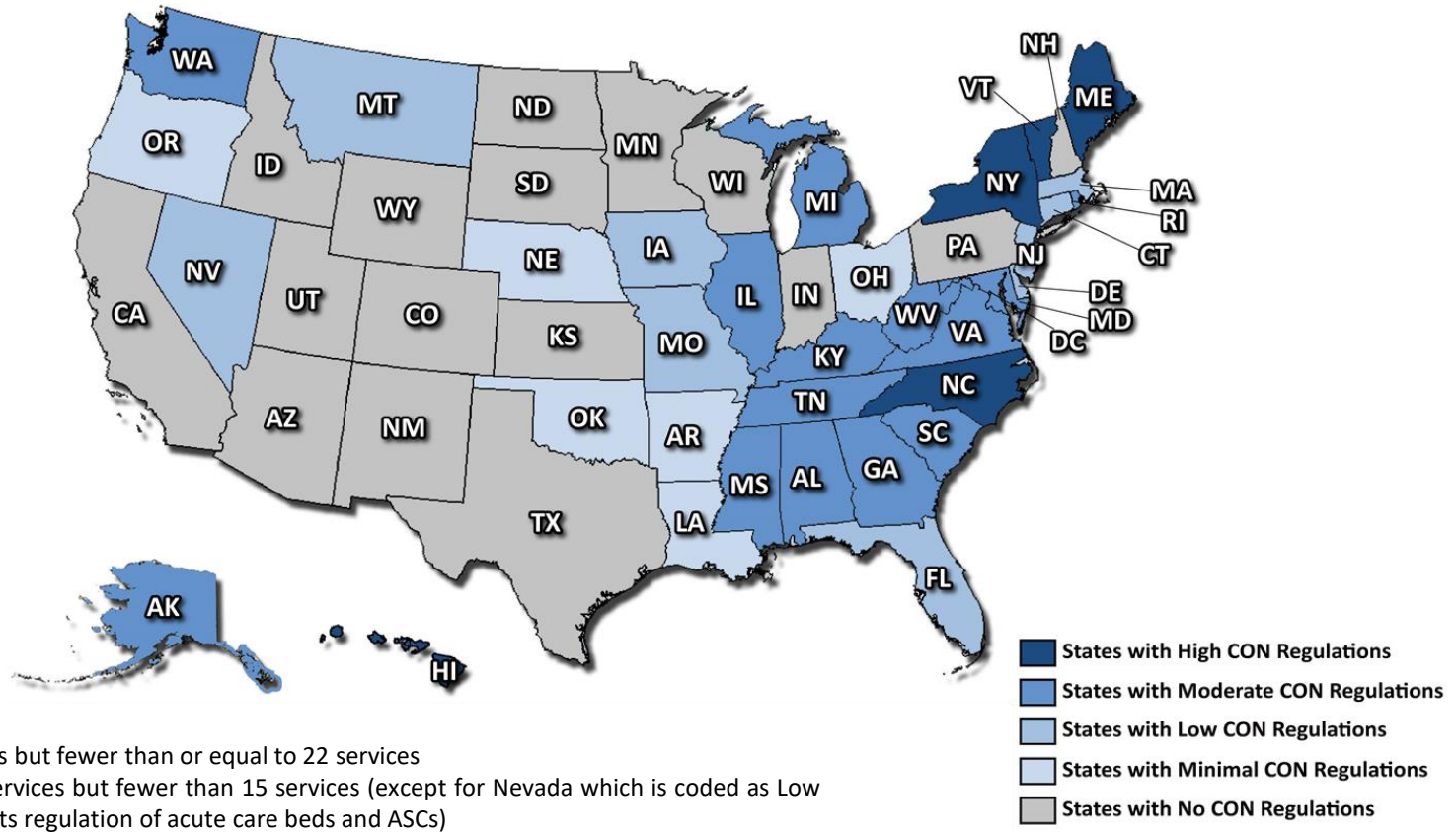
The Importance of CON: Presentation Guide

- First, A Caution
- Access to Healthcare Services
- Case Study Implications
- Policy Context
- Industry Instability & Transformation

First, A Caution: Not a Binary Choice

Any analysis that treats CON status as a binary choice—and most do—is grossly oversimplified. Among the 35 states with CON laws, there are huge variations in services covered, enforcement, administrative policies, and threshold levels. This also fails to consider several states with unique circumstances/outliers as well as ***the timing of CON repeal*** that may skew any simple analysis.



High: State regulates more than 22 services
Moderate: State regulates more than 15 services but fewer than or equal to 22 services
Low: State regulates more than or equal to 8 services but fewer than 15 services (except for Nevada which is coded as Low despite having only 6 regulated services due to its regulation of acute care beds and ASCs)
Minimal: State regulates fewer than 8 services and does not regulate hospitals, acute care beds, or ASCs

Source: American Health Planning Association 2011 and 2016 National Directory CON Programs Health Planning Agencies . Ascendient categories.

First, A Caution: Complex Relationships and Small Datasets

The size of datasets in any state-based CON analysis—which are limited to 51 states, including the District—**inherently limits the conclusions that can be drawn from these studies**.

10 to 20

vs

4

"[T]here are rules of thumb for how many observations one should have per regressor (variable). For example, textbooks typically suggest 10 to 20 observations per variable. I, personally, usually look for at least 20. [In this 2016 imaging analysis, two models] have 51 observations (50 states, plus the District of Columbia) for 12 variables (e.g., CON requirement, average age, etc.), or about 4 observations per variable. It means this model is at a high risk for overfitting, which means the results can be misleading because the model is too complicated for the size of the dataset. **The bottom line is that these results should not be interpreted without major caution."**

-Mark Holmes, PhD, Director Cecil G. Sheps Center for Health Services Research; Professor and Associate Chair, UNC Gillings School of Public Health

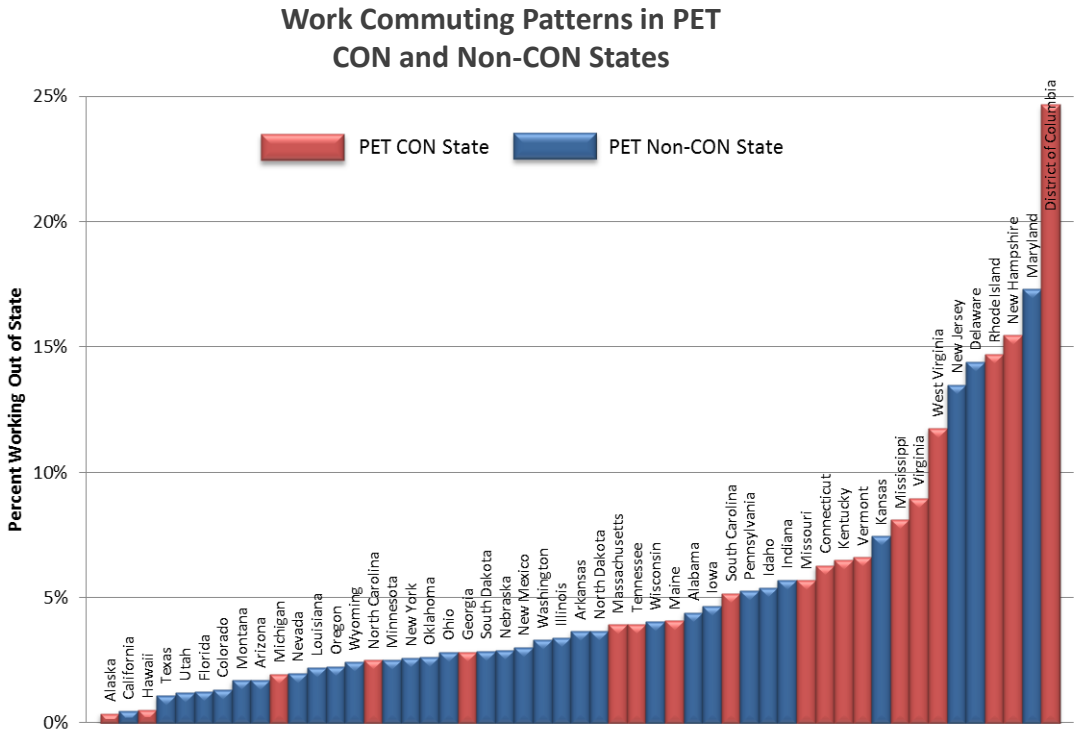
Sources: "Image vs Reality: Mercatus, CON, and Statistics in Search of Meaning," Ascendient Healthcare Advisors, May 2016. Referencing: Mercatus' "Are Certificate-of-Need Laws Barriers to Entry? How They Affect Access to MRI, CT, and PET Scans." January 2016

First, A Caution: Impossible to Conclude that CON Causes Particular Outcomes

"Studies…must be careful about drawing **conclusions about causation** from mere correlations."

-Mark Holmes, PhD, Director Cecil G. Sheps Center for Health Services Research; Professor and Associate Chair, UNC Gillings School of Public Health

The CON law isn't *causative* here—regulations aren't forcing you out of state for work, nor are they forcing you out of state for medical care. Instead, CON laws correspond strongly with denser populations and more fluid commuting patterns.



Dr. Holmes illustrates the danger in drawing such conclusions by analyzing the commuting patterns of each state's workforce with the imaging data from a 2016 study that stated: *"The propensity for residents of CON states to travel out of state to obtain medical services can be attributed to any of several factors: higher costs, a smaller selection of services, or lower access to care."*

"A false conclusion would be that CON for PET increases the probability of working in another state…Clearly, PET CON is not causal relative to the percentage of residents who work out of state. Rather, these states have high connectedness to other states for reasons other than CON, and those reasons are likely a major driver of the differences."

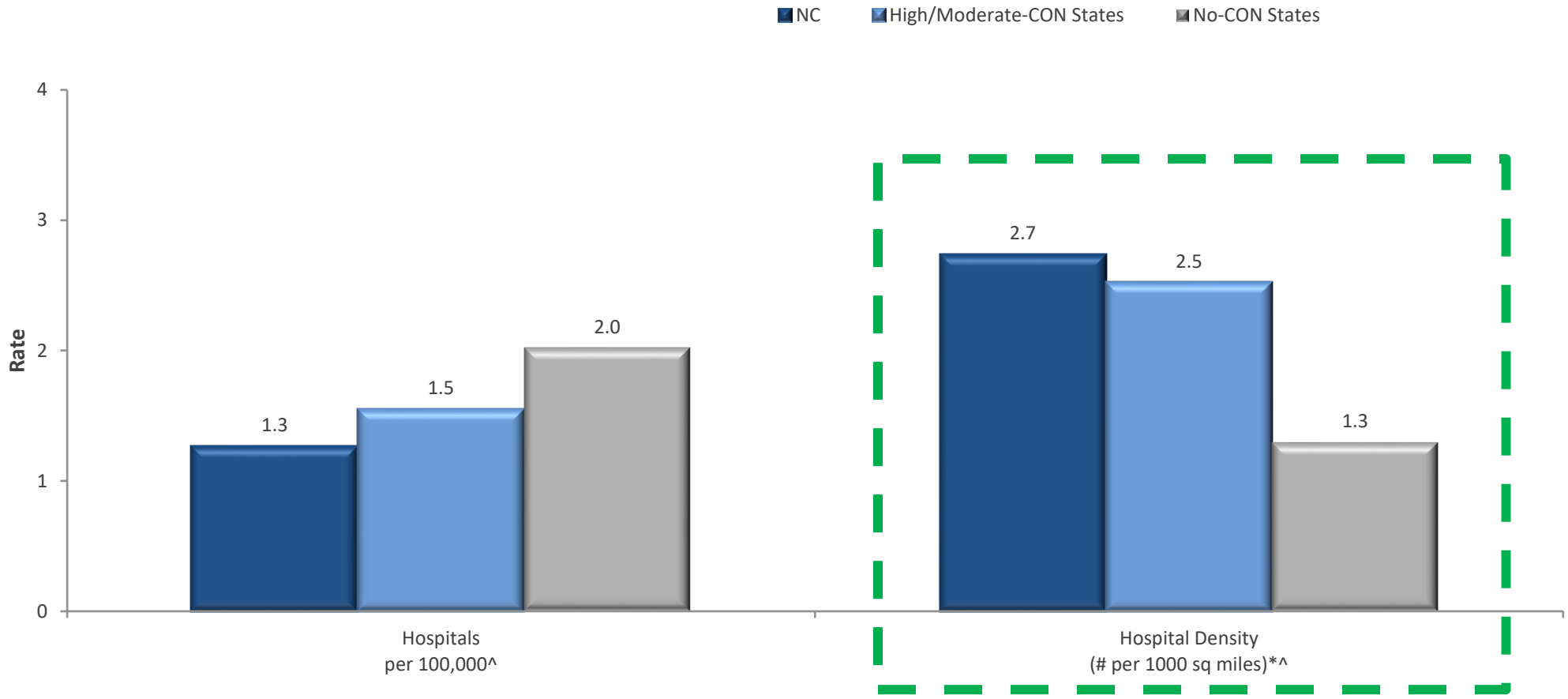
-Mark Holmes, PhD

Sources: "Image vs Reality: Mercatus, CON, and Statistics in Search of Meaning," Ascendient Healthcare Advisors, May 2016. Referencing: Mercatus' "Are Certificate-of-Need Laws Barriers to Entry? How They Affect Access to MRI, CT, and PET Scans." January 2016

Access to Healthcare Services

Access to Healthcare Services: Hospitals

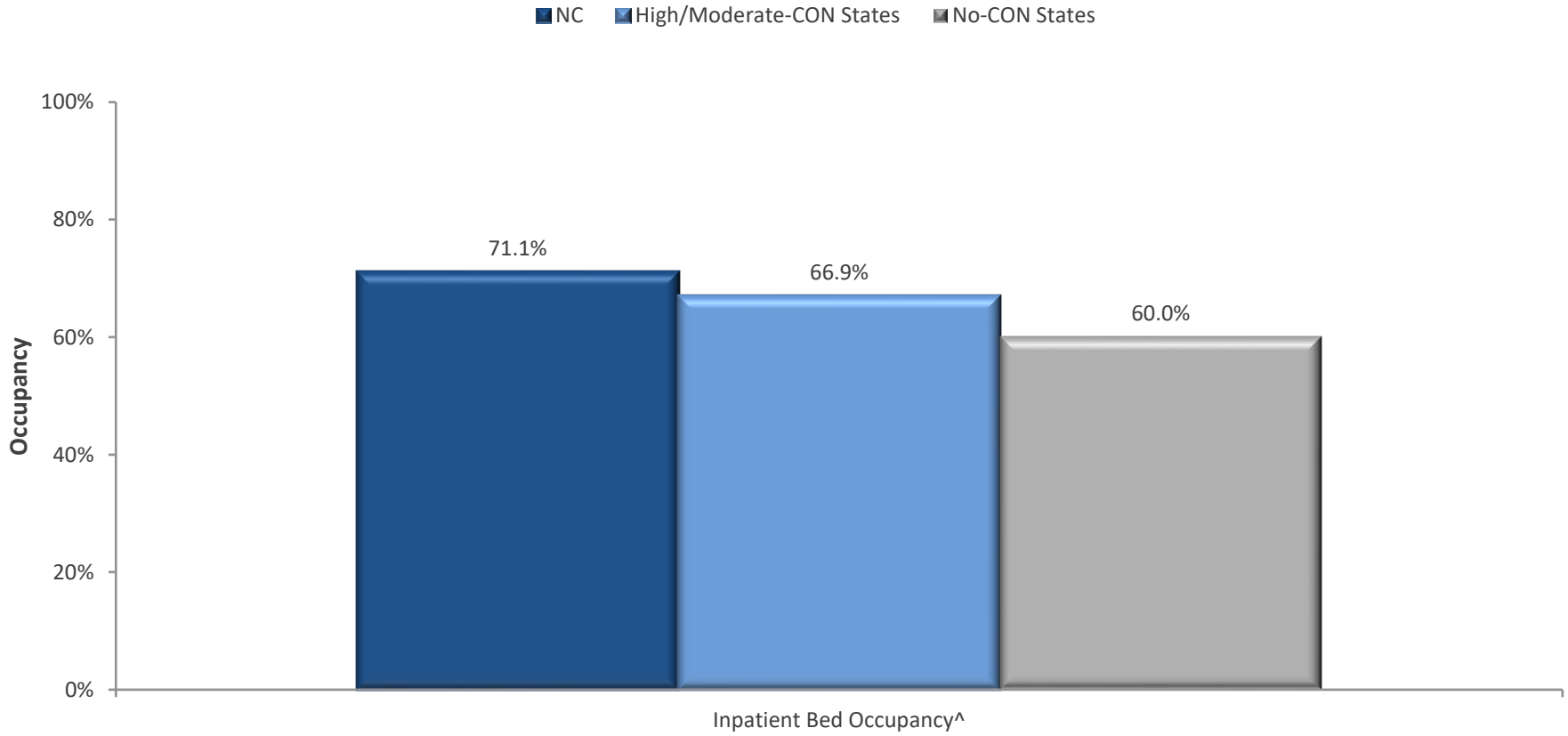
North Carolina and its High/Moderate peers have **better access to hospitals** than No-CON states.



*Denotes measures for which the District of Columbia was excluded.
^Denotes metrics that were statistically significant between High/Moderate-CON States and No-CON States.
Note: Data shown by degree of CON above are based on median values unless otherwise noted.
Sources: data.census.gov; AHA Data Query from FY 2019 AHA Annual Survey (excludes federal, VA hospitals and non-acute care hospitals).

Access to Healthcare Services: Hospital Efficiency

Hospitals in North Carolina and its High/Moderate-CON peers are **more efficient** than hospitals in No-CON states (statistically significant difference).



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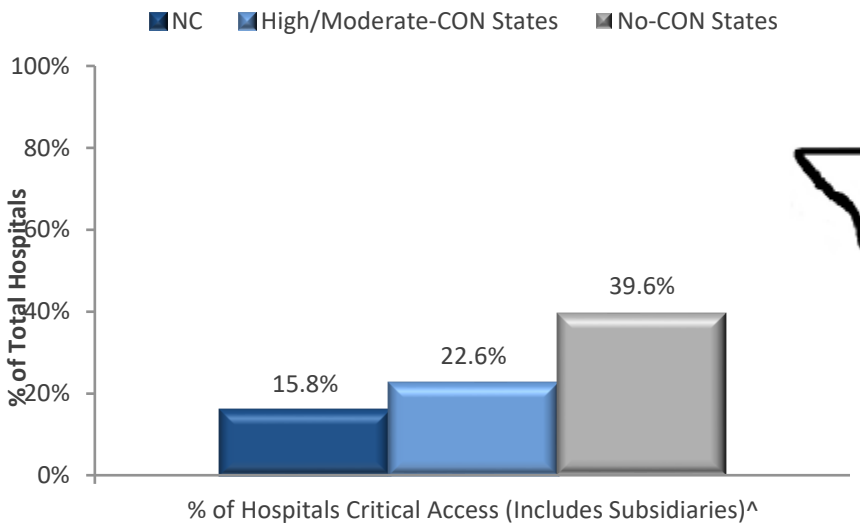
Source: AHA Data Query from FY 2019 AHA Annual Survey (excludes federal, VA hospitals and non-acute care hospitals.

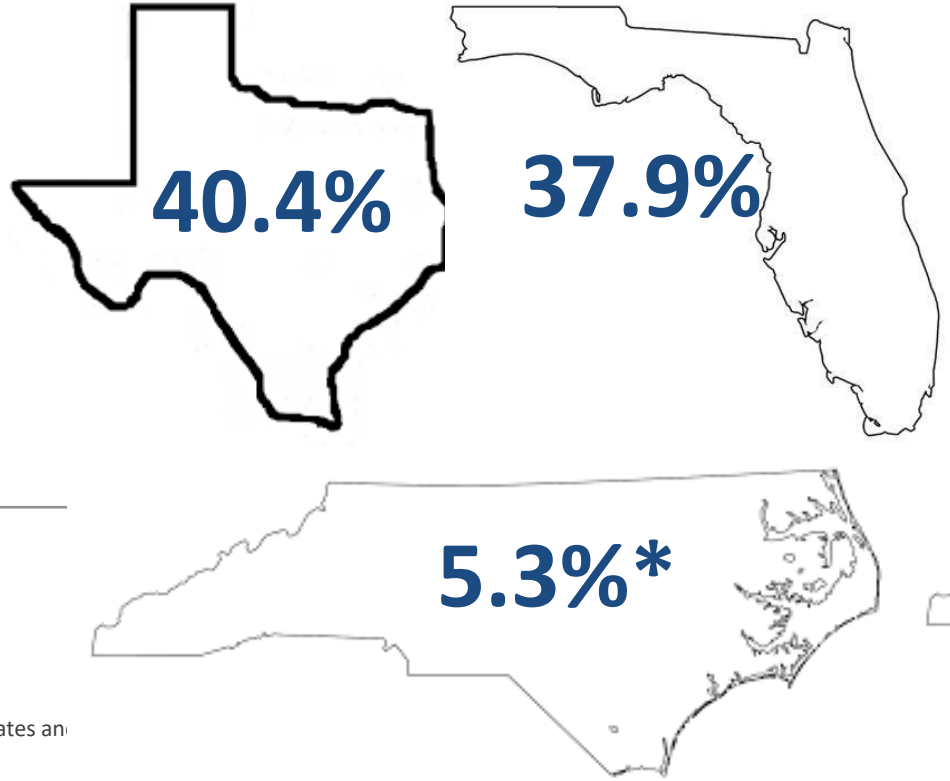
Access to Healthcare Services: Hospital Type

Compared with No-CON states, North Carolina has more general acute care hospitals that serve a broad range of patients under a prospective payment system.

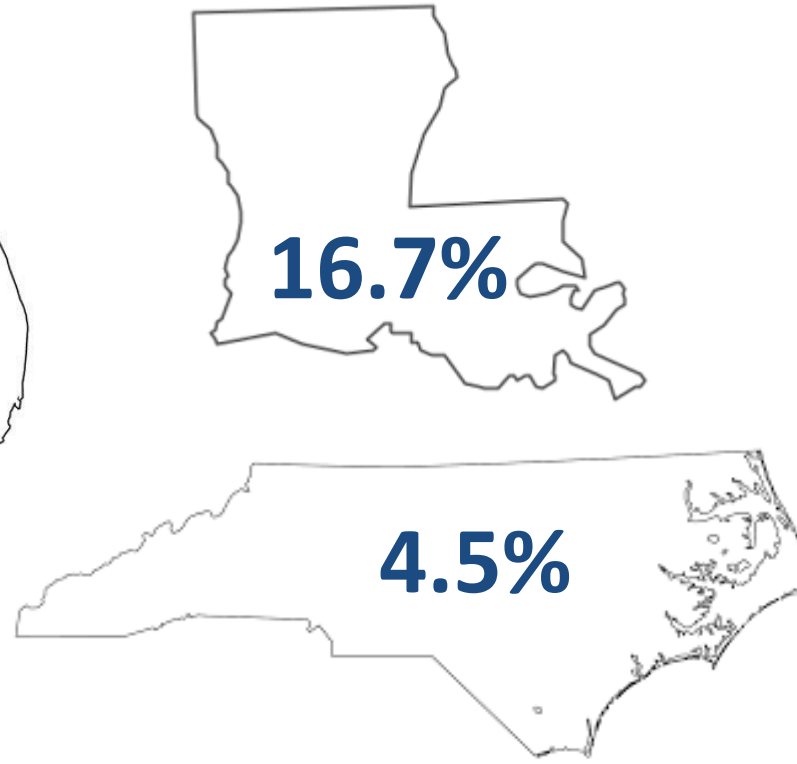
Critical Access Hospitals



Investor-Owned Hospitals



Specialty Hospitals



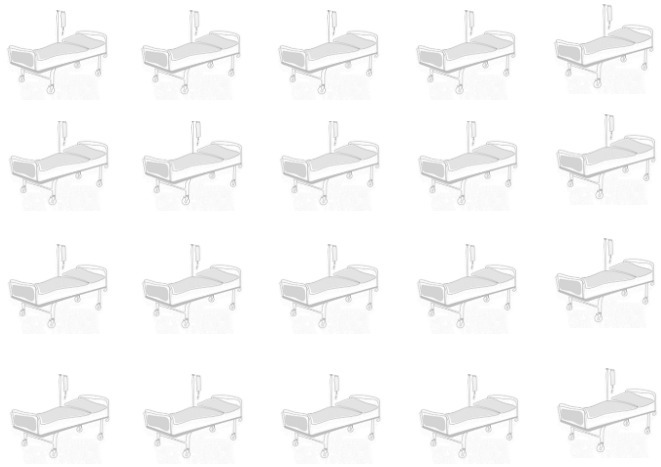
^Denotes metrics that were statistically significant between High/Moderate-CON States an
Note: Data shown by degree of CON above are based on average values.
*Data prior to HCA acquisition of Mission Health.
Source: AHA Data Query from FY 2019 AHA Annual Survey (excludes federal, VA hospitals and non-acute care hospitals

Access to Healthcare Services: Hospitals and Hospital Beds

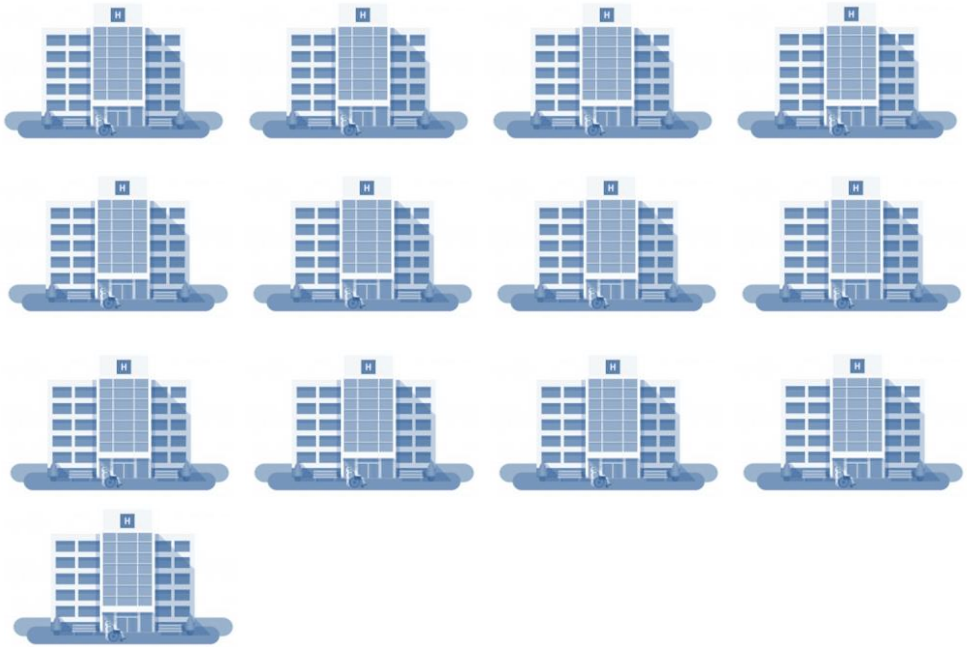
North Carolina CON has not impeded the addition of hospital or inpatient bed capacity when needed. CON did not preclude the temporary surge of nearly 5,000 beds during the COVID-19 emergency.

Since 2010, the SMFP has allocated **more than 2,200 new acute care** beds.

Of those applied for, all but 10 were awarded (93 were not applied for and 274 remain pending).



Since 2010, the CON Section has approved **13 new hospitals** in North Carolina.



Sources: State Medical Facilities Plans. NCDHSR, Healthcare Planning & Certificate of Need Section, Monthly Reports.

Access to Healthcare Services: Hospital Beds During COVID-19

CON status did not impact availability of beds during pandemic peaks. No-CON states' median occupancy was 60% pre-pandemic compared with over 70% for High/Moderate-CON states—suggesting that No-CON states should have had more available capacity to meet pandemic needs. However, **No-CON states' occupancy during the pandemic far outpaced** High/Moderate-CON states'.

	High/Moderate-CON States	No-CON States	North Carolina
Peak Census Occupancy Using Surge Bed Capacity	77.0%	73.8%	75.8%
Peak Census Occupancy Using Pre-Pandemic Bed Capacity	85.7%	96.1%	108.5%

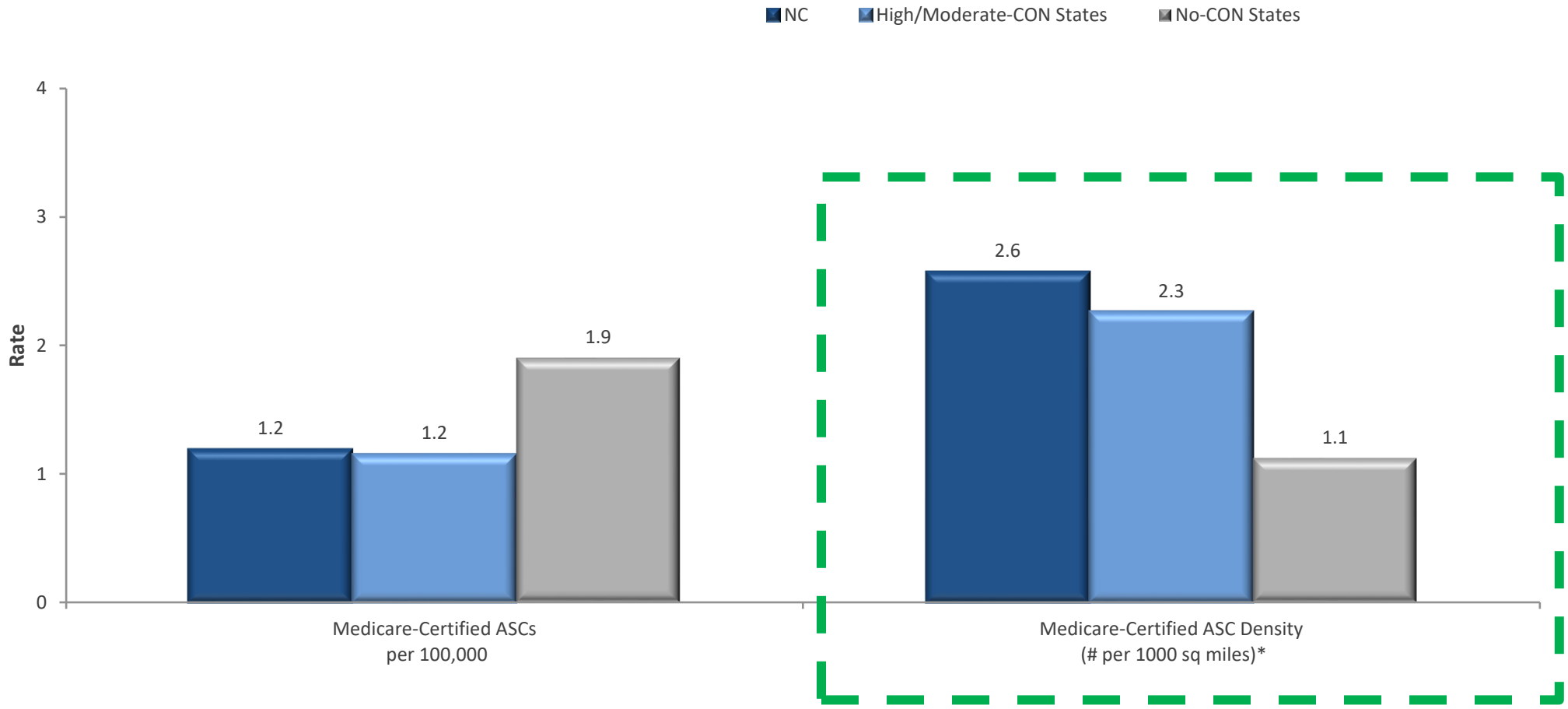
Note: Data shown by degree of CON above are based on average values.

60.8% ➡ 386.8%

^Denotes metrics that were statistically significant between High/Moderate-CON States and No-CON States.
Note: Data shown by degree of CON above are based on average values.
Source: COVID-19 Reported Patient Impact and Hospital Capacity by State Timeseries as provided by the U.S. Department of Health & Human Services, as of April 10, 2021.

Access to Healthcare Services: Ambulatory Surgery Centers

North Carolina and its High/Moderate peers have **better access to ASCs** than No-CON states.



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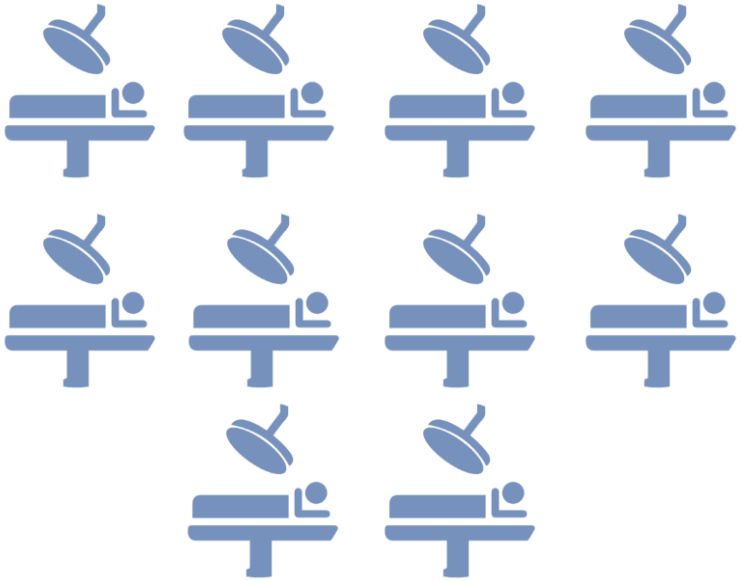
^Denotes metrics that were statistically significant between High/Moderate-CON States and No-CON States.
Note: Data shown by degree of CON above are based on median values unless otherwise noted.
Sources: data.census.gov; CMS, ASCA.

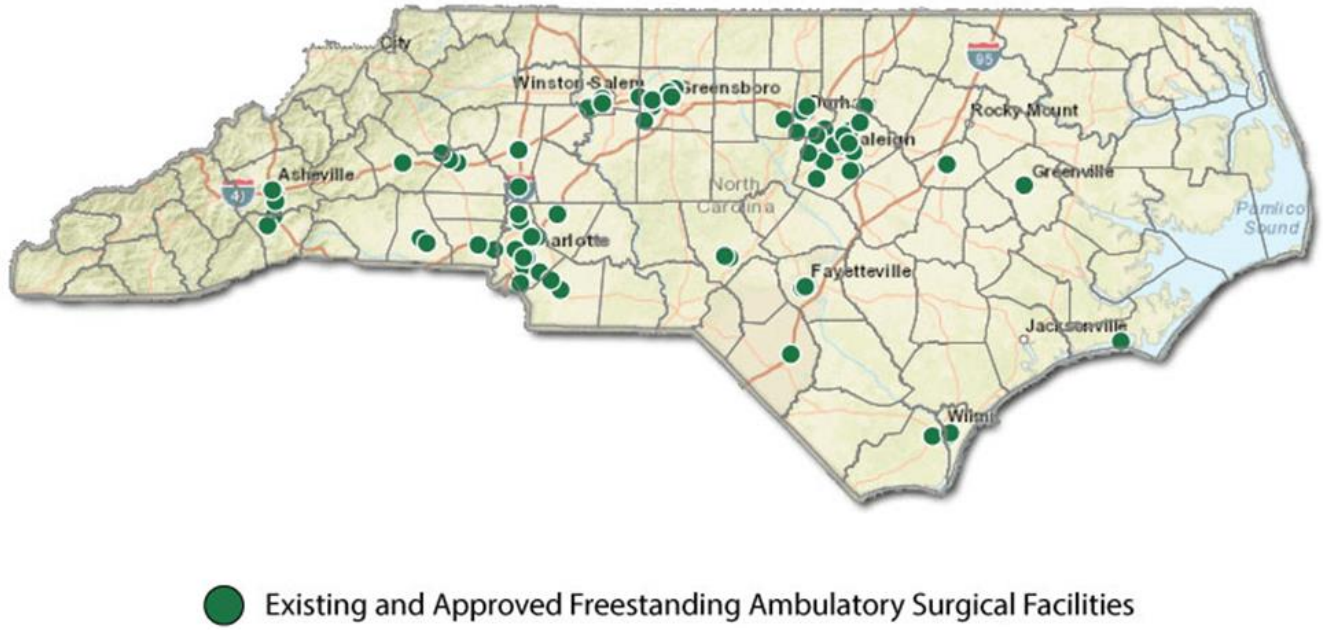
Access to Healthcare Services: Ambulatory Surgery Centers

North Carolina CON has not impeded the addition of operating rooms and ASCs when needed.

Since 2010, the *SMFP* has **allocated over 100** new operating rooms (over 80 in the last six years).



Since 2010, the CON Section has **approved 32 new freestanding ASFs**, with at least 50 operating rooms.



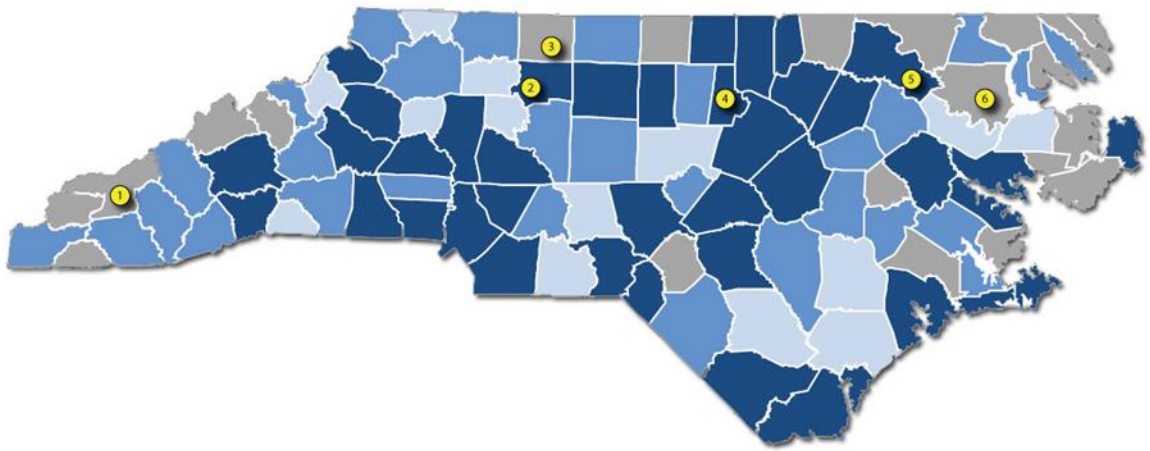
Existing and Approved Freestanding Ambulatory Surgical Facilities

Sources: State Medical Facilities Plans. NCDHSR, Healthcare Planning & Certificate of Need Section, Monthly Reports.

Access to Healthcare Services: MRI

North Carolinians have access to MRI services, in contrast to a 2015 analysis that suggested CON prevented 49 fewer hospitals in North Carolina from offering MRI services.

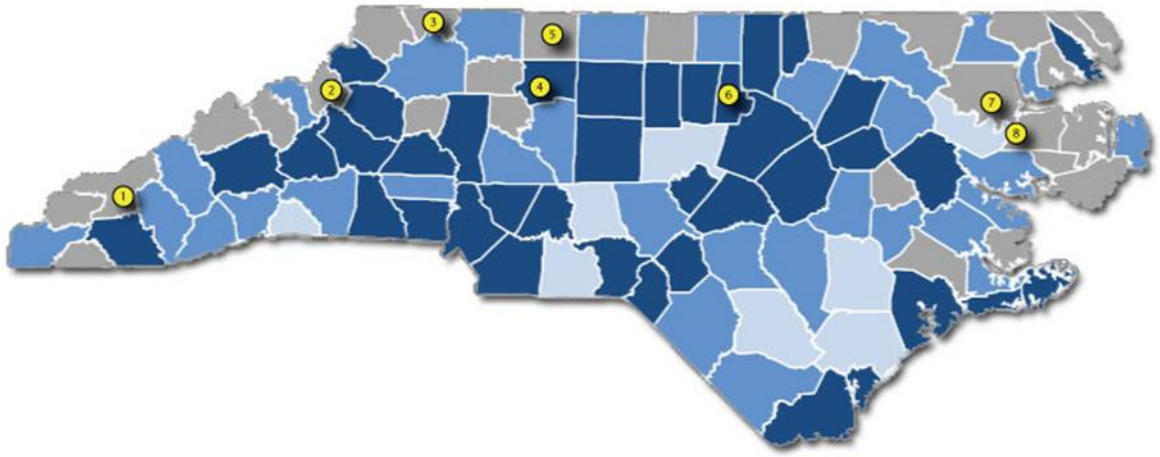
2015 MRI Access



- Fixed & Mobile MRI Services
- Fixed MRI Services
- Mobile MRI Services
- No MRI services

1. MedWest Swain
2. Novant Health Medical Park Hospital
3. Pioneer Community Hospital of Stokes
4. North Carolina Specialty Hospital
5. Our Community Hospital
6. Vidant Bertie Hospital

2022 MRI Access



- Fixed & Mobile MRI Services
- Fixed MRI Services
- Mobile MRI Services
- No MRI services

1. Swain Community Hospital
2. Charles A. Cannon, Jr. Memorial Hospital
3. Alleghany Memorial Hospital
4. Novant Health Medical Park Hospital
5. LifeBrite Community Hospital of Stokes
6. North Carolina Specialty Hospital
7. Vidant Bertie Hospital
8. Washington Regional Medical Center

Sources: "Data, Dollars and Danger: A 3D Analysis of Certificate of Need in North Carolina," Ascendient Healthcare Advisors, July 2015. Referencing: Koopman, C. and Stratmann, T., "Certificate-of-Need Laws: Implications for North Carolina," Mercatus on Policy, Mercatus Center, George Mason University, February 2015. *2022 State Medical Facilities Plan.*

Access to Healthcare Services: MRI and Other Imaging Services

CON repeal arguments are often more about who provides imaging services. Ample evidence exists to show that **physician-owned imaging centers tend to increase utilization**, perhaps even unnecessary utilization, and thus drive up system costs—precisely the outcome that CON regulators work to prevent.

GAO 2009 Study, Florida Findings

- Imaging center owners ordered **twice as many** MRI scans and 29 percent more CT scans for their patients than nonowners.
- Physicians with MRI machines in their offices ordered about **three times as many** MRI scans per 1,000 office visits as other physicians.

Laurence Baker, Stanford, 2008

- Acquiring an MRI scanner led to a **22 percent increase** in the probability of ordering MRI scans by orthopedic surgeons and a **28 percent increase** in the probability of ordering MRI scans by neurologists.

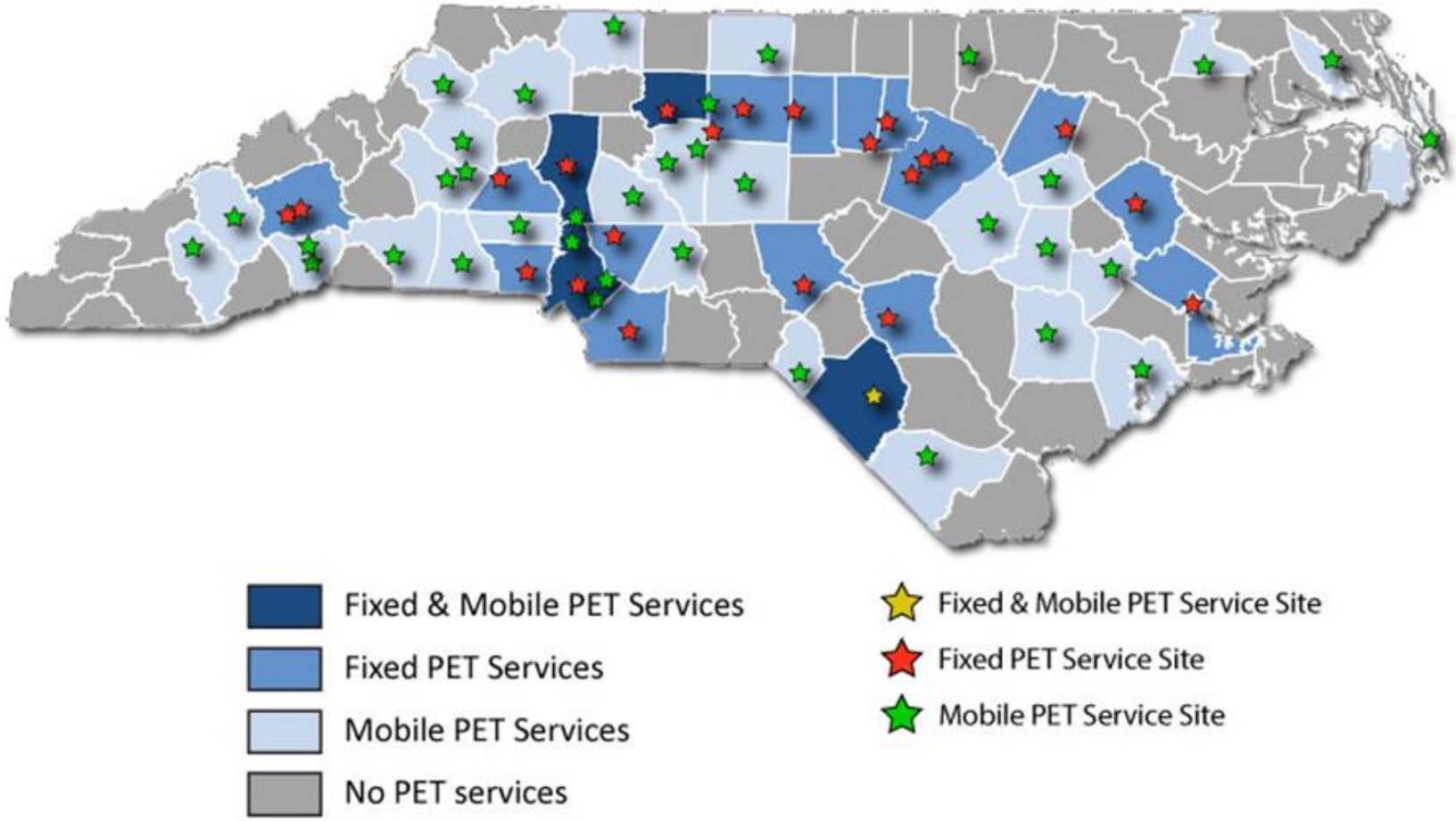
Swedlow, et al. CA Workers Comp, 1992

- Of the scans ordered by physicians with an ownership interest in an MRI facility, **38 percent** were determined to be inappropriate during a precertification review.
- By contrast, **28 percent** of the scans ordered by physicians without such an ownership interest were found to be inappropriate.

Source: "Impact of physician self-referral on use of imaging services within an episode," Report to the Congress: Improving Incentives in the Medicare Program, June 2009, http://67.59.137.244/chapters/Jun09_Ch04.pdf

Access to Healthcare Services: PET

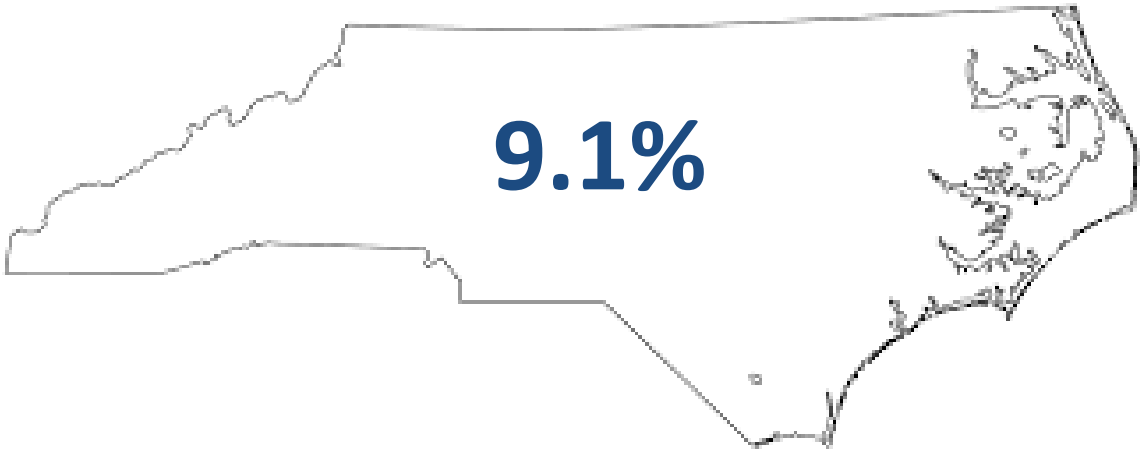
North Carolinians have strong access to specialized imaging, such as PET, including in more rural areas of the state.



Source: *2022 State Medical Facilities Plan.*

Access to Healthcare Services: Uncompensated Care

Uncompensated care provided by hospitals is **higher** in High/Moderate-CON states than in No-CON states. North Carolina provides even more.



No-CON States average **8.2%**

High/Moderate-CON States average **8.6%**

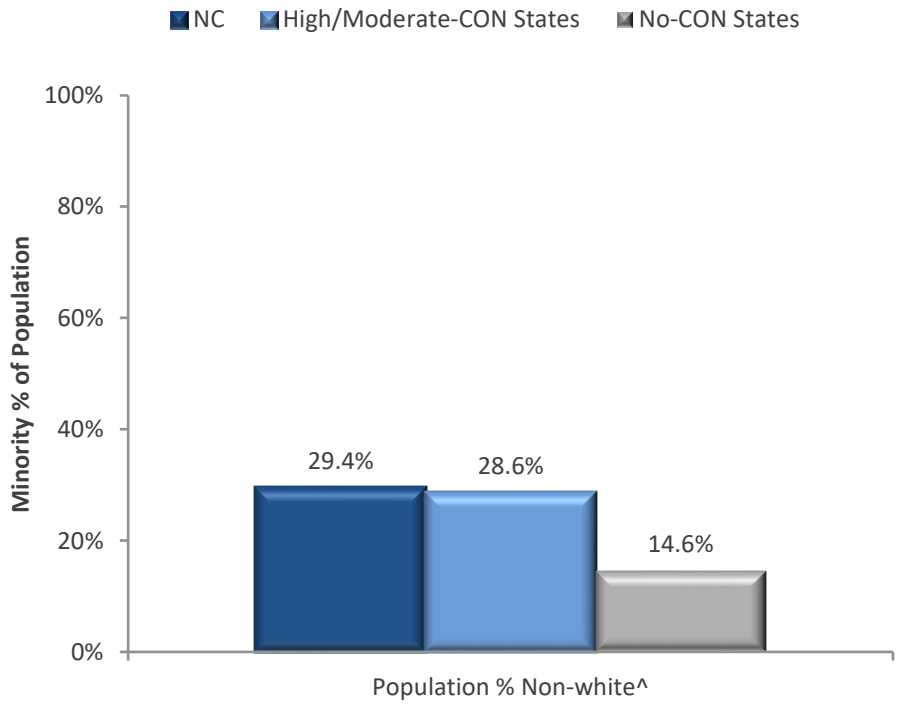
North Carolina averages **9.1%**

^Denotes metrics that were statistically significant between High/Moderate-CON States and No-CON States.
Note: Data shown by degree of CON above are based on average values.
Source: AHA Data Query from FY 2019 AHA Annual Survey (excludes federal, VA hospitals and non-acute care hospitals. AHA sourcing from CMS.

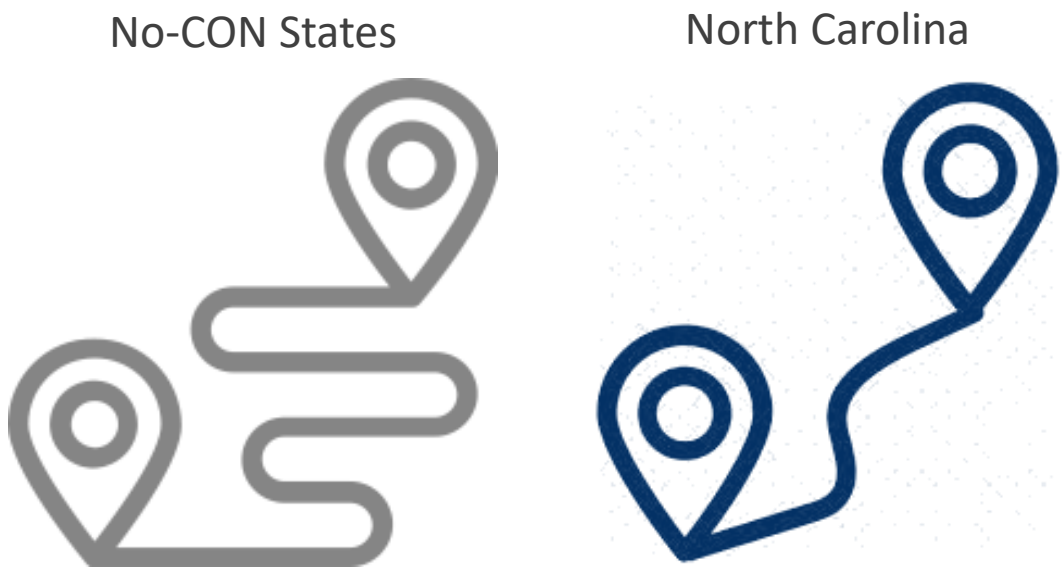
Access to Healthcare Services: Health Equity

The population in No-CON states is much **less diverse** (statistically significant) than High/Moderate-CON states. On average, High/Moderate-CON states have two times the proportion of non-whites as No-CON states.

Residents of counties without a hospital and with above average minority populations in No-CON states have to **travel 65% farther to the nearest hospital** than the same population in North Carolina.



Distance to Nearest Hospital



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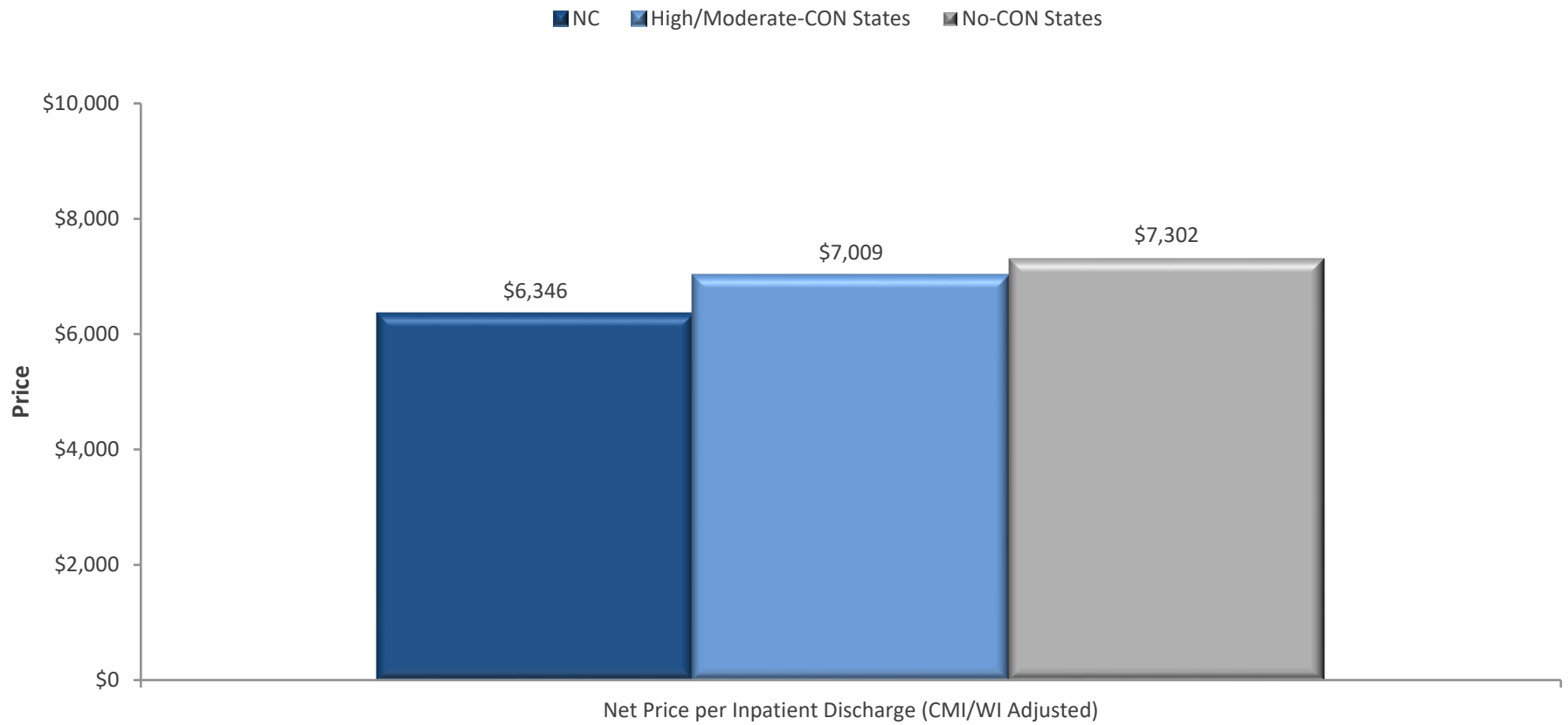
Note: Data shown by degree of CON above are based on average values.
Sources: data.census.gov; AHA Data Query from FY2019 AHA Annual Survey and Google Maps.

Access to Healthcare Services: Cost of Services

North Carolina and its High/Moderate peers **pay less for hospital inpatient** services than No-CON states.

North Carolina currently has the **13th lowest inpatient payment rate in the US**.

At No-CON median rates, payors would **pay almost $1 billion more per year** for hospital inpatient services in North Carolina.

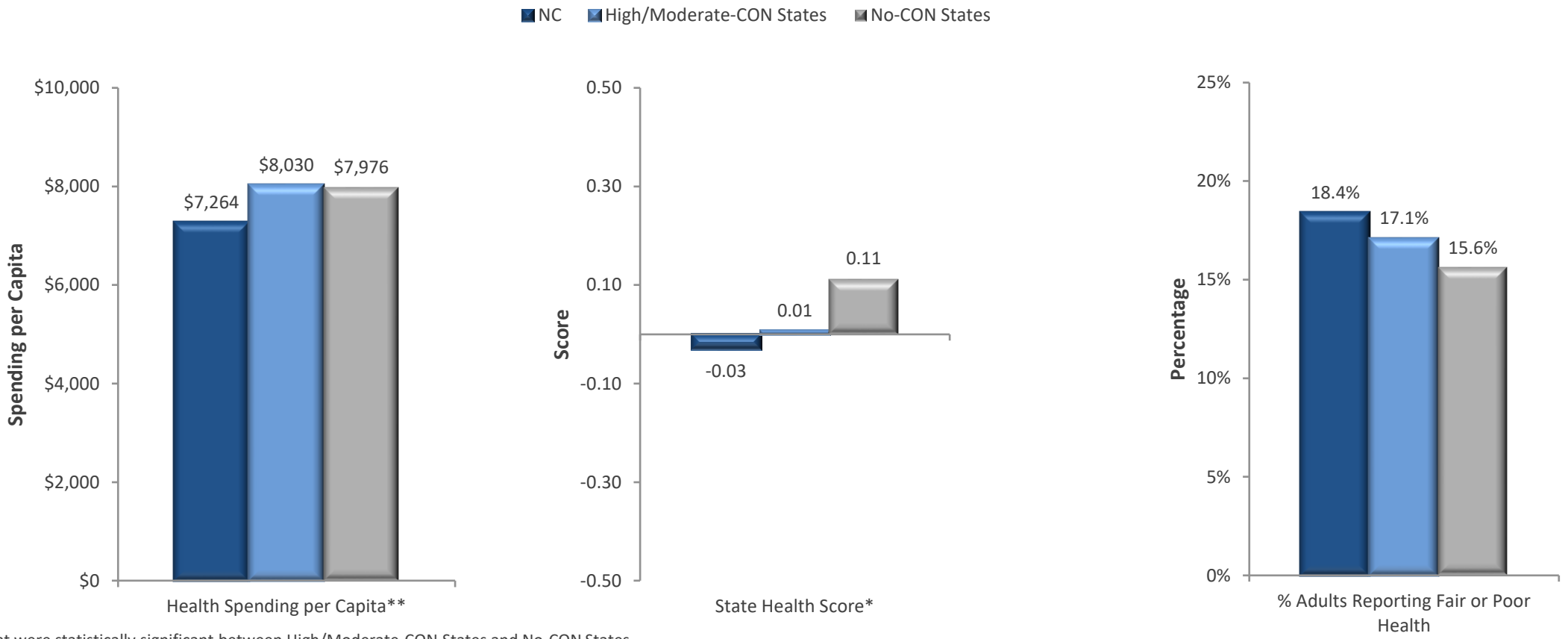


Note: Data shown by degree of CON above are based on median values unless otherwise noted.
Source: Optum Almanac, March 5, 2021 Data Release;

Access to Healthcare Services: Per Capita Spending and Population Health

North Carolina's per capita spending is lower than No-CON states and its High/Moderate-CON peers. North Carolina currently ranks **9th lowest** for per capita spending, despite poorer health status.

At No-CON median spending, North Carolina's spending would increase by **more than $7 billion per year.**



^Denotes metrics that were statistically significant between High/Moderate-CON States and No-CON States.
Note: Data shown by degree of CON above are based on median values unless otherwise noted.
Sources: Per capita data year is 2014 (most recent from KFF). Data pulled form Kaiser Family Foundation which reproduced data from the Centers for Medicare & Medicaid Services, Office of the Actuary National Health Statistics Group. National Health Expenditure Data: Health Expenditures by State of Residence, June 2017. United Health Foundation, America's Annual Report Health rankings. Behavioral Risk Factor Surveillance System (BRFSS), 2019

Case Study Implications

Case Study Implications: Rural vs Suburban/Urban

Case Study Implications: Rural Hospital Closures

Using profile data of closures from the NC Rural Health Research Program, at least half (25) of North Carolina's small rural and rural hospitals are already vulnerable, including two-thirds of all hospitals located in small rural communities.

North Carolina Hospitals	Small Rural		Rural		Total
	Critical Access Hospitals	Non-Critical Access Hospitals	Critical Access Hospitals	Non-Critical Access Hospitals	
# of Total NC Hospitals	9	3	11	27	**50**
Vulnerable NC Hospitals	8	-	8	9	**25**

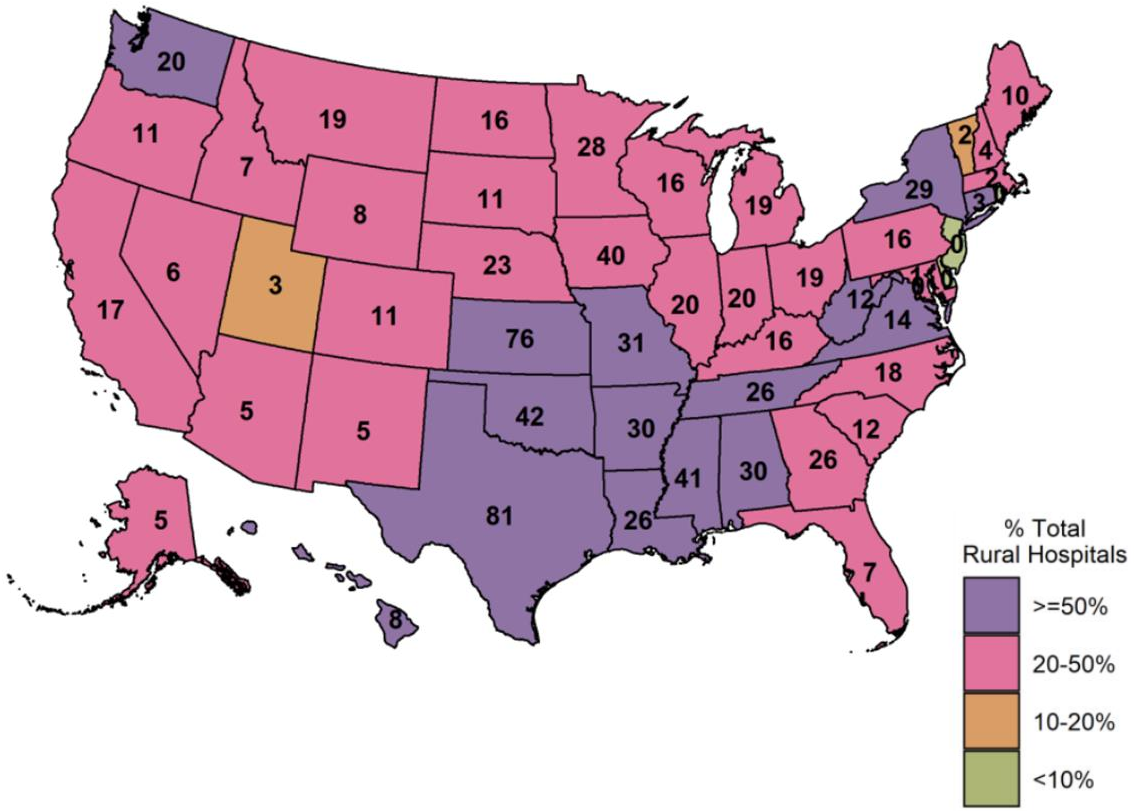
Together, these 25 hospitals represent:

- 25 counties with a combined population of nearly **892,750**
- Approximately **115 inpatients** each day
- More than **378,800** emergency department visits each year.

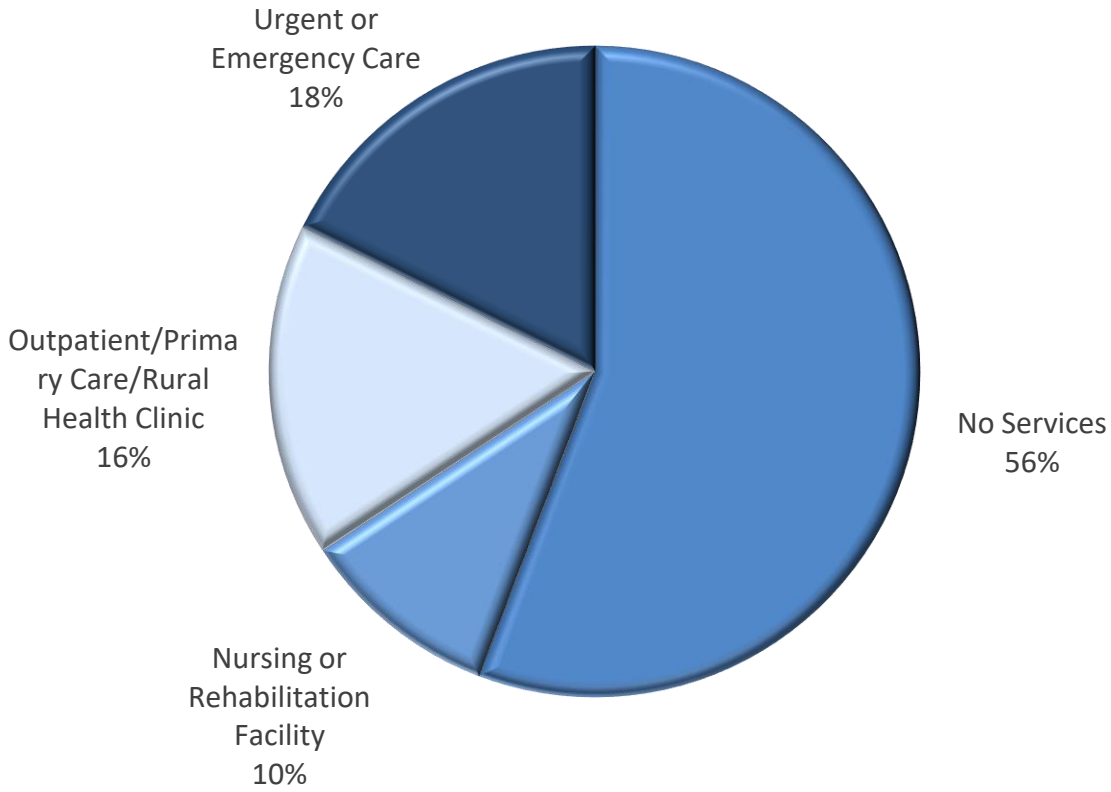
Sources: Ascendient analysis of closed hospital profiles as listed by NC Rural Health Research Program's Hospital Closures in Rural Geographies. data.census.gov; North Carolina Hospital License Renewal Applications.

Case Study Implications: Rural Hospital Closures

Center for Healthcare Quality and Payment Reform



Sheps Center: Status After Closure



Sources: Center for Healthcare Quality and Payment Reform; UNC: The Cecil G. Sheps Center for Health Services Research

Case Studies: CON Repeal

Although a number of factors typically contribute to rural hospital closures, the development of ASCs is likely a contributing factor…especially when the ASC capacity is not needed.

North Carolina residents would need to generate more than **one million *additional* surgical cases each year** to justify the new ASCs that would be developed based on the Georgia experience. To justify:

2 in 10

North Carolinians have surgery each year

OR

Everyone has surgery every 5 years

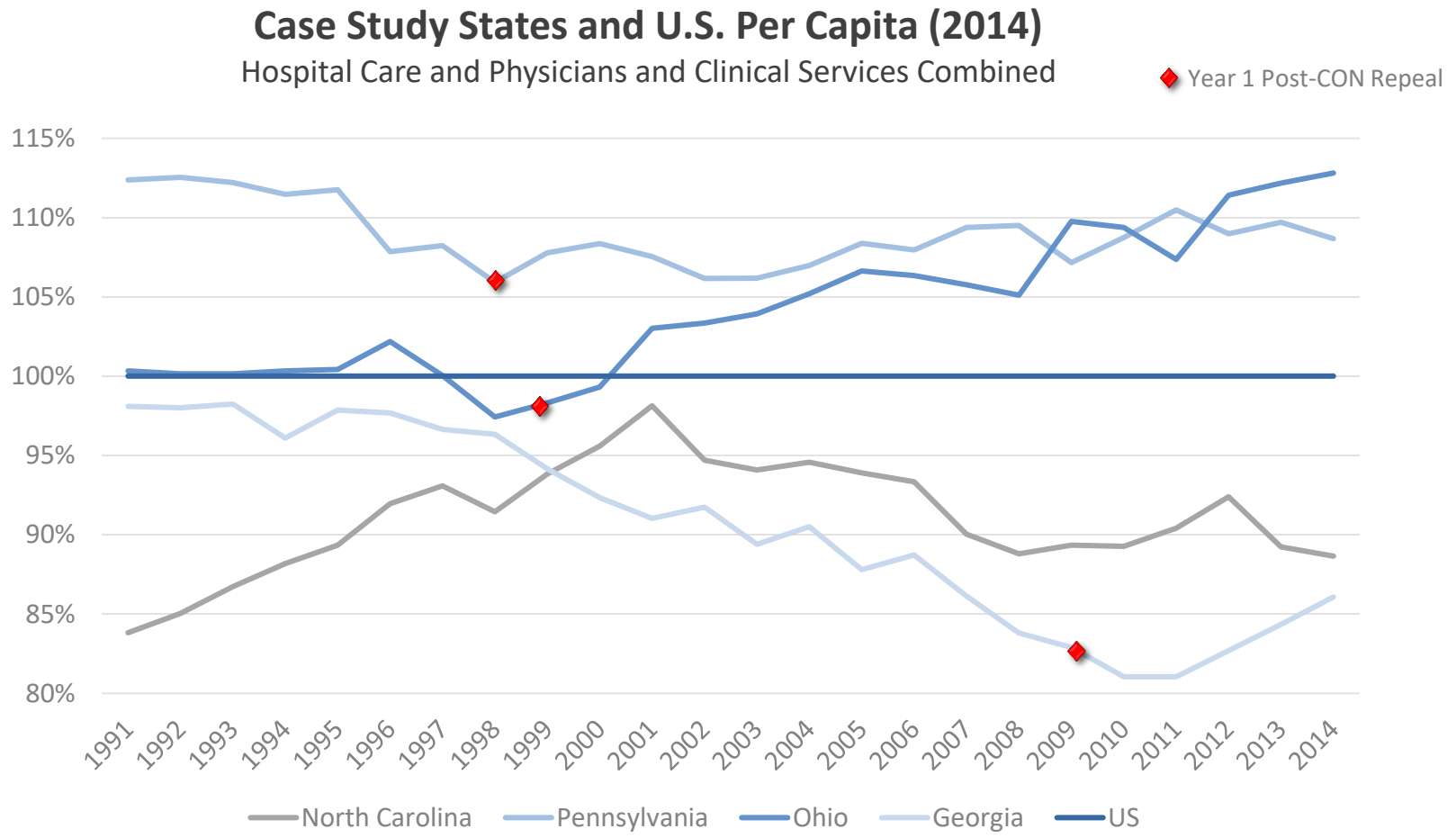
*NOTE RE PA IS SIMILAR RESULTS, BUT DATA SOURCE INCLUDED GI ENDOSCOPY

^Ohio data includes only those hospitals with Level I OB services that closed. Those 14 hospitals were 15% of the hospitals in Ohio.

Sources: GA Department of Community Health Annual Freestanding Ambulatory Surgery Center Survey Database, 2018; NC ASC information from the NC Division of Health Service Regulation, Licensed Facilities as of April 15, 2021; Pennsylvania Health Care Cost Commission Council Ambulatory Surgery Center Financial Analysis 2010, 2018, and 2019 Reports. Focus: An In-Depth Look at Issues Affecting Health Care, What's Happened in Ohio? Four Years Later, September 2001; Population data from the US Census population estimates by county. Ascendient estimates

Case Study Implications: Per Capita Health Expenditure Growth Rates Compared with US

In each of three case study states—Ohio, Pennsylvania, and Georgia—per capita health expenditures for hospital and physician services **grew at a higher rate in the years since CON repeal** than the US average growth rate over the same period of time. Prior to repeal, the states' expenditures had been growing at a rate lower than the US average.



North Carolina, consistently lower than the US average, would **increase at a rate ~20 percent above the national growth rate** with the repeal of CON, based on the experience of these states.

Source: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsStateHealthAccountsResidence.html. Ascendient analysis.

Case Study Implications: Urbanization and Overbuilding

CON repeal appears to contribute to the urbanization trend. According to a study of the Indianapolis metropolitan area completed by the Center for Studying Health System Change, the repeal of Indiana's CON law has allowed hospitals freedom to expand—in affluent suburban communities.

"The systems' growth follows the migration of well-insured patients to growing, affluent suburban communities…. According to a January 2010 Indiana Business Journal article, the Indianapolis area has added more than 900 staffed inpatient beds since 2000, a 17 percent increase….As a result of new building, ***inpatient capacity across the market has increased, particularly in well-insured, suburban communities****. Several observers suggested that the increased capacity is leading to rising utilization as hospitals seek to recoup investments by ensuring new facilities are running near capacity….****Some observers believed the community as a whole is now overbuilt, with new growth aimed mainly at winning the allegiance of well-insured patients****."*

Source: Katz, Aaron, Grace Anglin, Emily Carrier, Marisa K. Dowling, Lucy B. Stark, and Tracy Yee, Indianapolis Hospital Systems Compete for Well-Insured, Suburban Patients, Washington, D.C.: Center for Studying Health System Change, December 2011.

Case Study Implications: Urbanization and Overbuilding

Despite original intentions to expand access to rural, underserved communities (more than half of the state's 254 counties we define as small rural) **more than 80 percent** of Texas Freestanding Emergency Departments (FSEDs) are located in large suburban, urban, or large urban communities.

Freestanding Emergency Departments in Texas by Geography

Year	Small Rural	Rural	Rural Suburban	Suburban	Small Urban	Urban	Large Urban	Total
Total	-	9	15	15	39	25	106	209
% of Total	-	4.3%	7.2%	7.2%	18.7%	12.0%	50.7%	100.0%

^Year-to-date as of April 1, 2021.
Note: All geographic classifications based on current definitions.
Source: Texas Health and Human Services, Directory of Freestanding Emergency Medical Care Facilities as of April 1, 2021.

Policy Context

Policy Context: Barriers to Free Market Competition in Healthcare Will Persist

July 2004 FTC/DOJ report, "Improving Health Care: A Dose of Competition" notes the inherent features of US healthcare markets that limit competition.

"[C]ompetition remains less effective than possible in most health care markets, because the prerequisites for fully competitive markets are not fully satisfied…"

- **Extensive Regulation**

Remains intact and will continue to limit competition (e.g., anti-kickback, self-referral, EMTALA, and medical malpractice).

- **Third Party Payors**

Healthcare remains remarkably different from a "well-functioning market [that] maximizes consumer welfare when consumers make their own consumption decisions based on good information, clear preferences, and appropriate incentives."

- **Societal Attitudes**

"For most products, consumers' resources constrain their demand. Consumers and the general public do not generally expect vendors to provide services to those who cannot pay for them….By contrast, many members of the public and many health care providers view [and regulations such as EMTALA establish] health care as a 'special' good, not subject to normal market forces, with significant obligational norms to provide necessary care without regard to ability to pay."

- Information Problems
- Cost, Quality, and Access – The Iron Triangle
- Agency Relationships

*"Improving Health Care: A Dose of Competition" A Report by the Federal Trade Commission and the Department of Justice, July 2004.

Policy Context: Payment Transformation, A Critical Prerequisite

July 2004 FTC/DOJ report Recommendations include:

- *"**Payment methods** that give incentives for providers to lower costs, improve quality, and innovate could be powerful forces for improving competition in health care markets."*
- *"Governments should reexamine the role of subsidies in health care markets in light of their inefficiencies and potential to distort competition….Competition cannot provide resources to those who lack them; it does not work well when certain facilities are expected to use higher profits in certain areas to cross-subsidize uncompensated care. In general, **it is more efficient to provide subsidies directly to those who should receive them**, rather than to obscure cross subsidies and indirect subsidies in transactions that are not transparent. Governments should consider whether current subsidies best serve their citizens' health care needs."*
- *"States with Certificate of Need programs should reconsider whether these programs best serve their citizens' health care needs."*

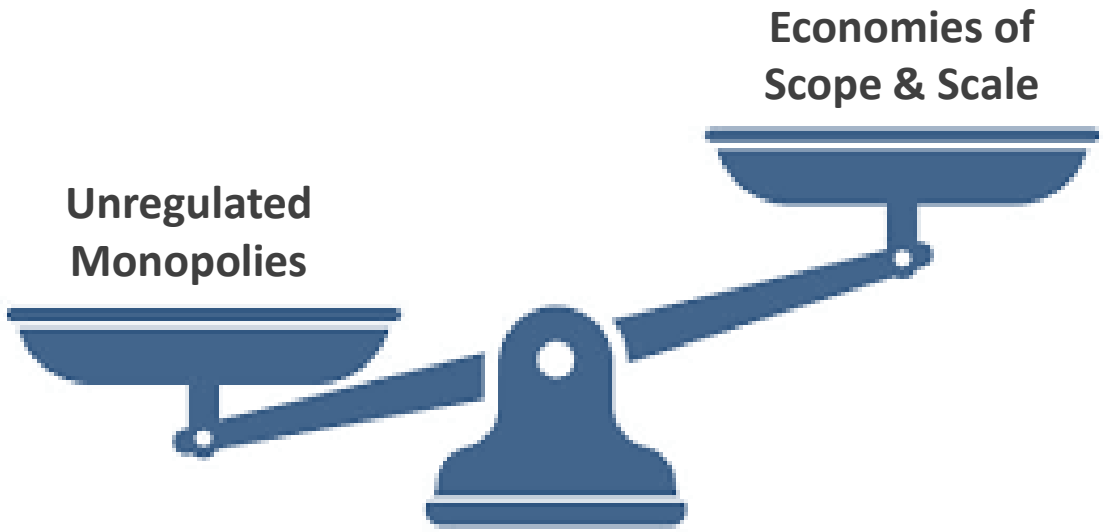
Referencing: "Improving Health Care: A Dose of Competition" A Report by the Federal Trade Commission and the Department of Justice, July 2004.

Policy Context: Competing Economic Arguments

The theoretical concern regarding monopoly pricing power has limited, and diminishing, applicability to healthcare providers.

"CON laws give health care providers the ability to take advantage of economies of scale and scope that can lower costs and increase quality. The basic question is which effect dominates and for which services."

"In general, economic theory suggests that unregulated monopolies have higher prices and lower quality than firms in more competitive markets. However, competition may limit the ability of facilities to exploit economics [sic] of scale and scope."



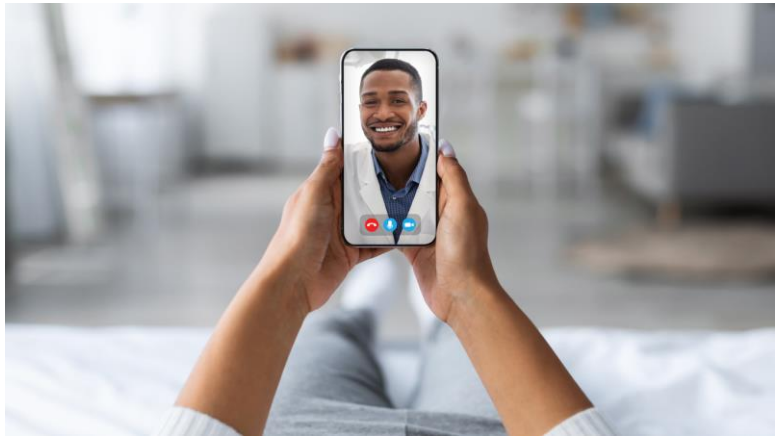
"Economies of scale occur when costs are reduced as volume increases. Economies of scope occur when it is less costly to produce two services together than each service separately."

Source: "Report of Data Analysis to the Georgia Commission on the Efficacy of the CON Program, Amended November 2006. As found: https://www.issuelab.org/resources/4667/4667.pdf

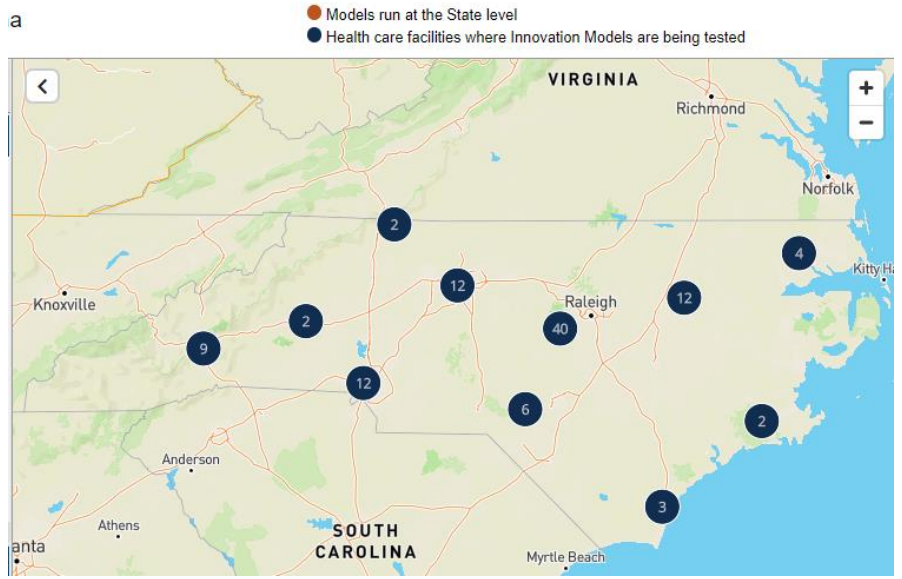
Industry Instability & Transformation

Industry Instability & Transformation

North Carolinians have **better access, lower inpatient prices and more uncompensated care** than No-CON states.
CON supports provider stability during this unprecedented time of uncertainty and transformation.



CMS Innovation Center Strategy:
All Medicare fee-for-service beneficiaries will be in a care relationship with accountability for quality and total cost of care by 2030.



Questions/Discussion